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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BIOGEN '755 PATENT LITIGATION	Civil Action No. 10-cv-02734 (CCC) (JBC) (consolidated) ORAL ARGUMENT REQUESTED

MEMORANDUM OF LAW IN SUPPORT OF
BAYER HEALTHCARE PHARMACEUTICALS INC.'S
MOTION FOR ATTORNEYS' FEES UNDER 35 U.S.C. § 285

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INTRODUCTION

This case is about a patent that Biogen never should have asserted. The one and only claim that Biogen asserted against Bayer has now been ruled invalid by a jury, the Federal Circuit, and the U.S. Patent and Trademark Office on multiple grounds—and those are just a few of the reasons why it is plainly invalid. Yet only after more than a decade of litigation on Biogen's multibillion-dollar infringement claim has Bayer finally prevailed, thanks in significant part to Biogen's frivolous arguments, shifting theories, and mischaracterizations of the facts and law. This is truly an exceptional case, and Bayer should be awarded its fees under 35 U.S.C. § 285.

This case is exceptional even focusing only on the issue on which the jury in the *Serono* case, and then the Federal Circuit, invalidated *all* the claims—not just the one in Bayer's case. Under the hornbook principle that "an old product is not patentable even if it is made by a new process," *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1366 (Fed. Cir. 2009), Biogen's claims are anticipated. The only difference between the treatment methods they claim and the prior-art use of natural interferon-beta is that Biogen's claimed polypeptides were made recombinantly—a (purportedly) new process. Biogen's own expert admitted in 2011, readily and repeatedly, that applying the definition in Biogen's patent, the polypeptide made recombinantly is exactly the same as natural interferon-beta; more than a century of clear and consistent precedent therefore mandated invalidity. Bayer moved for summary judgment on that exact issue—an issue on which the Federal Circuit agreed with Bayer's position in full—and Biogen's counterarguments were utterly meritless. Biogen asserted that claims like the one here to a method of using a product, rather than to a product itself, are exempt from this basic principle of anticipation, but as the Federal Circuit emphasized, Biogen's distinction "would defy all reason." *Biogen MA Inc. v. EMD Serono, Inc.*, 976 F.3d 1326, 1334 (Fed. Cir. 2020).

That alone suffices to make this case "exceptional." But in addition to the anticipation issue on which the *Serono* defendants ultimately prevailed, the sole claim asserted against Bayer faced a variety of additional, fatal flaws that the *Serono* case did not decide. Claim 1 recites a vast genus of polypeptides that the patent-in-suit's named inventor did not invent. Biogen could not assert the other claims of the '755 patent, which were the focus of the *Serono* case, because Betaseron is a different polypeptide from natural interferon-beta (and from Serono's and Biogen's products, both of which use the natural interferon-beta amino acid sequence). The breadth of claim 1 led to multiple invalidity grounds that Biogen managed to avoid, exceptionally and regrettably, only by playing fast and loose with the law and the facts.

First, the full scope of this claim lacks written description under 35 U.S.C. § 112. Biogen again deployed a meritless methods-are-different argument: according to Biogen, a party claiming a method can monopolize the use of a vast genus of polypeptides that it did not describe, even if it could never have claimed the same genus as compositions of matter. Like the argument that it lost in the context of anticipation, this "def[ies] all reason" and controlling Federal Circuit precedent. Biogen also ignored a wealth of precedent holding that claims—including method claims—to using large genera of products having unpredictable activity cannot possibly be supported by a single example, which is the most Biogen possessed. Indeed, all but one of the compounds within the vast genus of polypeptides, including Bayer's, were "muteins" that differed from the natural sequence, yet the patent does not contain a single mutein example, because the inventor never made, invented or enabled a single mutein.

Second, as the Patent and Trademark Office has found, claim 1 is invalid for obviousness-type double patenting. Biogen previously patented certain interferon-beta muteins and their use to treat viral diseases. By later obtaining the '755 patent-in-suit with a claim encompassing using those muteins to treat viral diseases, Biogen improperly extended its monopoly. Biogen's principal

response was the bizarre argument that the "two-way" double patenting test applied because the PTO was solely responsible for the delay during a "critical co-pendency period," *e.g.*, ECF 559 at 16-17, even though Biogen could have pursued, but chose not to pursue, its method-of-treatment claims for years. Biogen defeated summary judgment by asserting that the question of whether the one-way test or two-way test applies is a factual dispute, even though the law is clear that this is a pure question of law on which there *cannot* be a fact question.

And third, as to anticipation, Biogen's overbroad claim 1 encompasses yet *another* prior art method of treatment, the use of a different polypeptide, interferon-alpha. On this issue, Biogen staved off summary judgment by again recanting its own claim constructions, suppressing inconvenient experimental evidence—and making repeated misrepresentations to the Court.

These defenses are but a few of the ones that Bayer meritoriously raised, and Biogen baselessly opposed, over more than a decade of litigation. Even after the Federal Circuit invalidated the patent and issued its mandate, Biogen opposed entry of final judgment. Biogen has repeatedly and improperly led the Court away from a correct analysis of the law and a correct understanding of the facts, all to try to obtain a windfall on a product Bayer's predecessors uncontestedly developed by themselves and that had been on the market for sixteen years when Biogen's patent issued. If ever a case is "exceptional," it is this one. Bayer respectfully requests that the Court award Bayer its attorneys' fees in the amount of $25,261,412.64 under 35 U.S.C. § 285.

BACKGROUND

I. Interferon-Beta

As the Court is aware, this litigation involves a protein called interferon-beta ("IFN-β"), which is naturally found in human cells ("native IFN-β"). Green Decl., ¶¶ 40–42, ECF 582. IFN-β is made up of 166 amino acid building blocks, connected end-to-end in a linear array, which fold into three-dimensional proteins. *Id.* ¶¶ 32–33, 40. IFN-β has anti-viral properties and before the

priority date of the Fiers patent, was used to treat viral diseases. However, the human body only produces very small amounts of IFN-β. *See* U.S. Patent No. 7,588,755 (the '755 patent), col. 2, l. 53–col. 4, l. 22. In 1980, in response to this supply constraint, scientists found a way to express IFN-β polypeptides recombinantly ("recombinant IFN-β"). This new source vastly expanded IFN-β supplies and ultimately allowed pharmaceutical companies to use recombinant IFN-β as a treatment for, as relevant here, multiple sclerosis.

II. The '755 Patent and the Litigation in this Court

The only claim of the '755 patent at issue between Bayer and Biogen was claim 1, directed to a method of treating certain conditions by administering a recombinant polypeptide selected from an expansive genus. Claim 1 is exceedingly broad, because it defines which polypeptides are in or out by reference to a "hybridization" test: any recombinant polypeptide that displays antiviral activity and that is encoded by DNA that is "capable of hybridizing" to one of the recited DNA inserts is within the scope of the genus. Biogen's expert acknowledged that the number of polypeptides encoded by DNA that would meet the hybridization limitation—or "muteins"—is "many times larger than 19 to the 66th [power] . . . ," *i.e.*, trillions upon trillions. Green Tr. 610, 611:6-8, ECF No. 521-7.

When the '755 patent issued in 2009, Bayer's IFN-β product, Betaseron®, had been on the market for sixteen years. After Biogen threatened suit, Bayer filed this action on May 27, 2010, seeking a declaration of non-infringement. *See In re Biogen '755 Pat. Litig.*, 2018 WL 3613206, at *1 (D.N.J. July 26, 2018). On May 28, 2010, Biogen filed suit against, among others, Bayer and EMD Serono, Inc., alleging infringement of the '755 patent. *See id.*

In 2017, Serono and Bayer filed multiple motions for summary judgment, arguing that the underlying patent was invalid on a number of grounds. *See* Order Denying Mots. Summ. J. at 1, ECF No. 892. This Court denied those motions. *Id.*

After a five-week jury trial between Biogen and Serono, the jury rendered a verdict in February 2018 finding claims 1-3 anticipated. *See Serono*, 976 F.3d at 1330. This Court overturned the jury verdict of anticipation and conditionally ordered a new trial. *See id.*

III. The Reexamination

In December 2019, Bayer filed a request for *ex parte* reexamination, asserting that claim 1 was invalid for double patenting over claim 8 of U.S. Patent No. 6,127,332 ("the '332 patent."). *See* Reexamination No. 90/014,423, Request (Dec. 20, 2019) ("'423 Appl."), *available at* https://portal.uspto.gov/pair/PublicPair. The PTO granted Bayer's request, and in June 2020 issued a non-final rejection of claim 1 on double patenting grounds. '423 Appl., Non-Final Rejection (June 2, 2020). Following Biogen's response, the PTO in December 2020 issued another non-final rejection, maintaining the double patenting rejection of claim 1 and adding a rejection based on anticipation (in response to the Federal Circuit's decision on Serono's appeal, discussed below). '423 Appl., Non-Final Rejection (Dec. 10, 2020). Biogen again responded, defending claim 1 solely on the basis that the Federal Circuit was incorrect "for all of the reasons stated in its Petition for Panel Rehearing," but "otherwise not address[ing] the patentability of claim 1," and simply amending its application to add new claims 4-20. '423 Appl., Amend. & Resp. to Non-Final Office Action at 6-7 (Dec. 23, 2020); Suppl. Resp. (Dec. 31, 2010). Biogen did not even try to add any additional response to its position on double patenting. The reexamination remains pending.

IV. The Federal Circuit Appeal

Serono appealed this Court's grant of JMOL in favor of Biogen. Bayer filed an amicus brief in support of Biogen's position. In September 2020, the Federal Circuit reversed. *Serono*, 976 F.3d at 1337. The Federal Circuit noted that the native and recombinant versions of IFN-β polypeptide were exactly the same except for their sources—*i.e.*, the same except that the former is made naturally in the body and the latter is made in a laboratory. *See id.* at 1332-33. It disagreed with

Biogen's contention that the traditional "product-by-process" analysis should not apply to the '755 patent's method of treatment claims, emphasizing that "it would defy all reason" to credit this argument. *Id.* at 1333-34. The Federal Circuit also rejected Biogen's argument that the native polypeptide only anticipates the recombinant polypeptide if they have the same three-dimensional structure. *Id.* at 1335-36. It noted that, in the '755 patent, "the 'product' administered in the claimed method is the 'polypeptide.'" *Id.* Biogen explicitly defined the term "polypeptide" in the patent "with reference to its linear array," not its three-dimensional structure, and it was "undisputed that the prior art here teaches the administration of native IFN-β that has a linear amino acid sequence identical to the linear amino acid sequence of the recited recombinant" IFN-β. *Id.* Following longstanding precedent, the Federal Circuit held that native IFN-β anticipated identical-but-for-its-source recombinant IFN-β, and remanded with instructions to reinstate the jury verdict.

V. Final Judgment

In response to the Federal Circuit's mandate, Serono submitted a proposed final judgment. ECF Nos. 1110, 1112; *see also* Bayer Letter (Jan. 8, 2021), ECF No. 1114. Rather than seek a stay of the mandate to pursue further relief, Biogen asked this Court to delay entry of judgment while the PTO reviewed its "proposed new claims" that, if granted, "would render irrelevant the Federal Circuit's invalidity determination." Biogen Letter (Jan. 11, 2021) at 1, ECF No. 1115. Serono responded that this Court was obligated to execute the mandate, ECF No. 1116, but Biogen—without attempting to refute Serono's point—reiterated its request for a delay, ECF No. 1123 at 1. On March 8, 2021, this Court entered final judgment in favor of Serono and Bayer. ECF No. 1127.

ARGUMENT

In a patent infringement case, a district court "may award reasonable attorney fees to the prevailing party" if it determines that the case is "exceptional." 35 U.S.C. § 285. The Supreme Court has explained that an "exceptional case" is

> simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated. District courts may determine whether a case is "exceptional" in the case-by-case exercise of their discretion, considering the totality of the circumstances.

Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 554 (2014). Cases may be deemed "exceptional" under § 285 based on factors including the weakness of the losing party's litigation positions and its "presentation of contradictory expert testimony," *Oplus Techs., Ltd. v. Vizio, Inc.*, 782 F.3d 1371, 1374-75 (Fed. Cir. 2015); the losing party's misrepresentations to the court, withholding of testimony or documentation, and advancement of "frivolous and unsupported allegations," *MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 915-21 (Fed. Cir. 2012); and the losing party's "misrepresentation of Federal Circuit authority" and reversals of prior representations regarding the patent's disclosure, *ICU Med., Inc. v. Alaris Med. Sys., Inc.,* 558 F.3d 1368, 1380 (Fed. Cir. 2009). The Supreme Court has clarified that there "is no precise rule or formula" for deeming a case "exceptional." *Octane*, 572 U.S. at 554.[1]

Many of the factors that routinely support an exceptional case finding are present in this decade-long litigation about a single claim. Biogen's litigating position was remarkably weak; not only has claim 1 been invalidated by a jury and the Federal Circuit and been rejected on an additional ground by the Patent and Trademark Office, but those were just a couple of the many bases for finding claim 1 invalid (and not infringed) that Bayer asserted. From the outset, Biogen's claim was meritless. And Biogen litigated in an "unreasonable manner." Its arguments to avoid judgment throughout this litigation were unmoored from the evidence, the testimony of its experts, and

[1] The substantive strength of a party's litigating position is not fixed at any point in time. Rather, a patentee must "continually assess the soundness of pending infringement claims" as the case unfolds. *Taurus IP, LLC v. DaimlerChrysler Corp.*, 726 F.3d 1306, 1328 (Fed. Cir. 2013).

relevant legal authority. Biogen's ongoing attempts to maintain its frivolous suit against Bayer entitle Bayer to an exceptional case finding under § 285 and an award of attorneys' fees.

I. Biogen's Arguments Against Anticipation Over the Use of Native Interferon-Beta Were Unreasonable.

At summary judgment, Bayer argued that claim 1 was anticipated by prior art treatment with native IFN-β. In response, Biogen adopted a baseless theory that because it had drafted its claim as a method of treatment, it was exempt from the usual rules regarding how claims to old product limitations made by new processes should be analyzed. And on the merits, it reneged on the parties' agreed-upon definition of "polypeptide"—the exact definition that appears in the patent—in favor of a focus on the polypeptide's three-dimensional structure that appears nowhere in the '755 patent. Biogen also ignored its own expert's testimony that, applying the patent's definition to which Biogen had agreed, the recombinant IFN-β polypeptide is structurally the same as native IFN-β and differs only with respect to its source, a fact which doomed claim 1 under governing law, as the Federal Circuit recognized. Biogen's willful evasion of black-letter law and disregard for its own agreed-upon claim construction and the undisputed facts is, even without more, enough to make this an exceptional case.

A. Biogen's Argument that Claim 1 Was Not an Old Product Made by a New Process Was Baseless.

Long-standing precedent holds that "an old product is not patentable even if it is made by a new process." *Serono*, 976 F.3d at 1332 (quoting *Amgen*, 580 F.3d at 1366). There was no support for Biogen's legal theory that the novelty of the polypeptide limitation was exempt from this rule simply because the old product was a limitation of a method-of-treatment claim where the treatment was admittedly known, rather than the entire subject matter of the claim. The Federal Circuit rejected this argument out of hand:

> Biogen's only basis for novelty of the method of treatment claims at issue here is the novelty of the recombinant IFN-β composition that is administered. That composition

> is claimed in terms of the process by which it is manufactured. If the novelty of the recombinant IFN-β *composition* requires comparing its structure to the structure of native IFN-β, as *Amgen* requires, ***it would defy all reason to excuse that analysis*** for a method of administration claim using that composition . . . ***There is no logical reason why the nesting of a product-by-process limitation within a method of treatment claim should change how novelty of that limitation is evaluated***.

Id. at 1334 (emphasis added). Theories that "defy all reason" are exactly the type of "frivolous theories" that render cases exceptional. *See MarcTec,* 664 F.3d at 917, 918.

B. Biogen Agreed to the Patent's Express Definition of "Polypeptide" Then Abandoned that Position When It Became Clear that It Would Lose.

Biogen's arguments to this Court about whether the polypeptide was new were rejected with similar force by the Federal Circuit. Biogen agreed during claim construction that the patent's express definition of "polypeptide" was controlling. "Polypeptide" was defined as "a linear array of amino acids connected one to the other by peptide bonds between the α-amino and carboxy groups of adjacent amino acids." ECF No. 100-1 at 2; '755 patent at 8:62-64. This agreed definition was plainly correct, because Biogen "elected to be a lexicographer by providing an explicit definition in the specification for a claim term"; in such circumstances, "the definition selected by the patent applicant controls." *Renishaw PLC v. Marposs Società per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998)

After agreeing to this definition, however, Biogen disavowed it, because it rendered the patent invalid. Under the agreed construction, native and recombinant IFN-β are the same polypeptide, meaning that prior-art uses of native IFN-β anticipate the '755 patent. Biogen's ensuing position—which no intrinsic evidence supports—was that the claims in the '755 patent meet the novelty requirement based the recombinant IFN-β's three-dimensional structure. The Federal Circuit correctly rejected this argument out of hand. *See Serono*, 976 F.3d at 1336.

The parties' experts also agreed that the patent's definition referred to the "primary structure" or "primary sequence" of amino acids that comprise the IFN-β polypeptide. Biogen's own expert clearly and repeatedly confirmed that this definition is directed only to the primary

amino acid sequence, not a higher order protein structure. *See* Jackson Decl. ¶ 3, ECF No. 147 ("'[P]olypeptide' . . . tends to be used to refer to a sequence of amino acids linked by peptide bonds . . . without any chemical modifications to the amino acids and with no implication about its three-dimensional conformation."); Jackson Tr. 161:10-16; 162:22-163:4; 262:11-263:5, ECF No. 514-8; *see also* Jackson Tr. 39:5-8 ("[T]he complete amino acid sequence, the primary structure and the polypeptide are all interchangeable terms, I believe, in terms of the definition given there in '755."). Applying the patent's definition, he further agreed that in the relevant mature form, the "*polypeptides in both native and recombinant beta interferon*, regardless of the host system in which the protein was produced," are "*identical*." Jackson Tr. 39:16-23, ECF No. 514-8 (emphases added). That should have ended the case. Because the natural and recombinant IFN-β polypeptides are identical, and Biogen never disputed that natural IFN-β had been used as an antiviral treatment in the prior art, this prior-art treatment with native IFN-β anticipated Biogen's claim to treatment with recombinant IFN-β. *See* Bayer Mot. Summ. J. No. 2 at 26-29, ECF No. 522-19.

Biogen survived summary judgment, however, by adopting a position that conflicted with the claim construction, its expert's assertions, and, as the Federal Circuit confirmed on appeal, controlling law. Biogen argued that the term "polypeptide" "includes a protein's primary sequence as well as its secondary and tertiary structure, and any modifications such as glycosylation." Opp. Mot. Summ. J. No. 2, at 24, ECF No. 563 (citing Green Decl. ¶¶ 35–38, ECF No. 564; Garcia Decl. ¶¶ 20-21, ECF No. 573). Biogen further argued that the anti-viral properties of a polypeptide depend on more than its primary structure and so, to meet the anti-viral property limitation in the '755 patent, a polypeptide must be "folded into the correct three-dimensional structure"—none of which is in the patent. *Id.* at 4.

On appeal in the Serono case, the Federal Circuit soundly rejected Biogen's argument: "Biogen draws the wrong conclusion from the claimed antiviral activity limitation" because "the

claims, in calling for antiviral activity, do not recite any specific folded three-dimensional structure that gives rise to that activity." *Serono*, 976 F.3d at 1336. It continued:

> While it is indisputable that an amino acid sequence alone cannot give rise to antiviral activity, it is also indisputable that every linear sequence of amino acids will fold into *some* three-dimensional configuration. The claimed antiviral activity can arise from the administration of any three-dimensional protein with a linear amino acid sequence identical to the claimed recombinant "polypeptide."

Id. at 1336. The Federal Circuit then described Biogen's attempt to shoehorn the non-existent protein structure limitation into the "anti-viral activity" and "therapeutically effective" limitations as "incorrect" because that reading would "fail[] to give effect to Biogen's explicit definition of 'polypeptide' in the specification." *Id.* (citing *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009).

The Federal Circuit has affirmed fee awards in similar circumstances where a losing party takes shifting and baseless litigation positions. *See ICU Medical,* 558 F.3d at 1380-81 (affirming fee award under § 285 in part because patentee's amended complaint made an objectively baseless assertion). That Biogen survived summary judgment is of no moment; where a district court rules in favor of a losing party at the "summary judgment stage . . . due to false or misleading representations," such as Biogen's misstatements of the law and mischaracterizations of its own claim construction, the decision does not offer the losing party any support for the reasonableness of its positions under 35 U.S.C. § 285. *Medtronic Navigation, Inc. v. BrainLAB Medizinische Computersysteme GmbH*, 603 F.3d 943, 954 (Fed. Cir. 2010). Biogen's brazen disregard for the express definition of "polypeptide" and the testimony of its own expert, and its shifting and baseless litigation positions, warrant a similar award of fees here.

II. Biogen Avoided Invalidity by Inventing Limitations to Try to Narrow the Staggering Scope of Its Claims and by Ignoring its Experts' Testimony.

The '755 patent never complied with 35 U.S.C. § 112's written description requirement. Claim 1 purports to encompass trillions of possible polypeptides but does nothing to describe them.

In an attempt to avoid its failure to meet the written description requirement, Biogen again resorted to inventing baseless new law—arguing, without any legal or even policy support, that method of treatment claims are excepted from the law of 35 U.S.C. § 112. According to Biogen, § 112 did not require the patent to describe the full scope of the polypeptide genus used in the treatment method, despite clearly contrary precedent. Biogen also again shoehorned new claim limitations into previously agreed constructions, arguing—with no textual support whatsoever—that the '755 patent only covered polypeptides "closely related to" IFN-β, despite clearly contrary testimony from Biogen's own experts. Biogen's unreasonable positions and untenably broad claim provide further support for a finding of exceptionality.

A. To begin with, in its opposition to Bayer's motion for summary judgment of invalidity for lack of written description, Biogen relied on the startling proposition that "the proper inquiry for method of treatment claims" does not require "possession of the genus of drugs" recited in the claims. ECF No. 560 at 26. No case permits a patentee to exclude others from using a genus that is not described or known simply by claiming the administration of compounds in the genus rather than the compounds themselves. On the contrary, the Federal Circuit clearly requires patentees to enable and describe the full scope of compositions used in method claims: "Regardless [of] whether a compound is claimed *per se* or a method is claimed that entails the use of the compound," the patent must "provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds," because the distinction between claims to a genus of compounds and a method of administering those compounds "is a semantic distinction without a difference." *Univ. of Rochester v. G.D. Searle*, 358 F.3d 916, 926, 929 (Fed. Cir. 2004). And while Biogen evaded this proposition by citing to a district court case, *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 2016 WL 6138124 (E.D. Tex. Oct. 21, 2016), that case plainly has no application where, as here, it is the compounds rather than the method that is purportedly novel, *see Auto Techs.*

Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1283 (Fed. Cir. 2007) ("[T]he novel aspect of an invention must be enabled."); *Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1379 (Fed. Cir. 2017) (noting that the Federal Circuit has "generally eschewed judicial exceptions to the written description requirement based on the subject matter of the claims"). And even if it did, it does not support Biogen's position; the jury in that case was instructed consistently with the law Bayer cited, and inconsistently with Biogen's fabricated legal theory. The *UroPep* court instructed the jury that to satisfy the written description requirement, the patent must "include[] a sufficient number of representative compounds or a common structural feature so that a person of ordinary skill in the art would understand, from reading the patent, that the inventor invented the full scope of the claimed method." *UroPep*, 2:15-cv-01202-WCB (E.D. Tex. Apr. 25, 2017), D.I. 346, at 1427. Biogen's argument that method of treatment claims are somehow exempt from the written description requirement was unsupported by precedent, including the precedent it cited, and was nothing less than misdirection.

B. On the merits, the scope of claim 1 of the '755 patent is indefensible, and Biogen's attempts to defend it ignored binding precedent and imported limitations into the claim that had no support whatsoever. Claim 1 defines polypeptides falling within its scope by two properties: (1) the DNA that encodes the polypeptide must be "capable of hybridizing to any of" certain DNA sequences (the "hybridization limitation") and (2) the encoded polypeptide must display "antiviral activity" (the "antiviral activity limitation"). '755 patent col. 50:1-8. DNA sequences can hybridize even when their amino acid sequences differ. *See* Green Tr. 567:18-568:18, ECF No. 521-7.[2]

[2] This is the reason Biogen could assert infringement of Claim 1 by Bayer's Betaseron® product in the first place. Betaseron® was genetically engineered to have an amino acid and DNA sequence that differs from IFN-β, but it can still fall within the scope of the claim. Ravetch Rep. ¶¶ 65, 1006, ECF No. 515-3; Green Rep. at ¶¶ 173, 192, 196-197, 201-203, ECF No. 514-13. In other words, the '755 patent's grossly overbroad written description is the very hook that facilitated this litigation.

Biogen's expert acknowledged that the number of polypeptides encoded by DNA (the "muteins") that would meet the hybridization limitation is "many times larger than 19 to the 66th [power] . . . ," *i.e.*, trillions upon trillions. Green Tr. 611:6-8, ECF No. 521-7.

Description of a genus requires disclosure of either "a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad Pharma. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc); *Boston Scientific Corp. v. Johnson & Johnson* 647 F.3d 1353, 1367 (Fed. Cir. 2011) (claims to "tens of thousands" of possible analogs of drug invalid, because "[t]he patent laws do not reward an inventor's invitation to other researchers to discover which of the thousands of . . . analogs . . . could conceivably work").

As Bayer pointed out, and Biogen's own expert agreed, the '755 patent discloses neither of these. The patent discloses a polypeptide and DNA sequence for one and only one species within the genus: IFN-β. Green Tr. 615:22-24, ECF No. 521-7. There is not a single example of any of the trillions upon trillions of muteins, such as Bayer's polypeptide. This is legally insufficient to claim an entire genus: "one compound . . . cannot be said to be representative of a densely populated genus." *In re Alonso*, 545 F.3d 1015, 1021 (Fed. Cir. 2008); *see also Boston Sci.*, 647 F.3d at 1364 (rapamycin insufficiently representative of genus of rapamycin and its analogs). Certainly the lack of *any* examples of muteins cannot be sufficient.

Nor did the patent disclose "structural features common to the members of the genus." *Ariad*, 598 F.3d at 1350. At most, the hybridization limitation required only that *some portion* of the DNA sequence that encodes the polypeptide have *some* similarity to some portion of the DNA sequence of one of the DNA inserts recited in the claim, but polypeptides that met the limitation may have nothing in common. The functional antiviral activity limitation was also insufficient, because it did "not convey to a person of skill what structures the recombinant polypeptides have,"

Green Tr. 622:12-16, ECF No. 521-7, and did not convey to the POSA any information about *which* of those nearly innumerable muteins would be active, much less what "structural features" were "common to the members of the genus" that have antiviral activity. *Ariad*, 598 F.3d at 1350; Green Tr. 613:18-25, 615:22-616:3, 621:13-20, 622:17-623:2, ECF No. 521-7.

Biogen's unreasonable response further supports a finding of exceptionality. Astonishingly, Biogen asserted to the Court that, under claim 1, "only DNA sequences that are almost identical, or 'homologous,' can hybridize to each another," so the claim must only cover a "polypeptide made using a DNA molecule that is nearly identical to a DNA" molecule that encodes human IFN-β. Opp. Mot. Summ. J. No. 3 at 9, ECF No. 560. This was a misrepresentation; Biogen's own expert testified entirely to the contrary. As Dr. Green, Biogen's expert, observed, if a polypeptide has "a stretch of 100, any hundred," amino acids in common with IFN-β, "the other 66 amino acids *can be anything*," and so the hybridization requirement encompasses a number of polypeptides "*many times larger than 19 to the 66th*." Green Tr. 611 (emphasis added), ECF No. 521-7. That vast universe of polypeptides cannot by any reasonable stretch of the imagination be considered "identical or nearly identical" to IFN-β. Nor can the antiviral activity limitation salvage Biogen's argument. It misleadingly asserted that a mutein within the claims had to have "*[human]IFN-β-like* antiviral activity," Opp. Mot. Summ. J. No. 3 at 9–10, ECF No. 560—when the plain language of the claims merely requires *any* antiviral activity. And it utterly ignored its own expert's admission that the patent provides "no guidance" about which of the vast genus of muteins meeting the hybridization requirement "would be active." Green Tr. 621, ECF No. 521-7.

In short, Biogen's position that claim 1 has written description support was unusually weak, and its attempts to defend that position were baseless in multiple respects.

III. The '755 Patent Was Clearly Invalid for Obviousness-Type Double Patenting Over the '332 Patent.

The sweeping breadth of claim 1 also rendered it invalid for obviousness-type double patenting over the claims of Biogen's '332 patent, a ground on which the PTO has now agreed repeatedly with Bayer's position and rejected the claim. That doctrine bars "an inventor from extending his right to exclude through claims in a later-expiring patent that are not patentably distinct from the claims of the inventor's earlier-expiring patent." *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1210 (Fed. Cir. 2014). In the earlier-expiring '332 patent, Biogen claimed certain IFN-β muteins that it discovered—long after the work leading to the '755 patent—had activity. By later obtaining in the '755 patent a broad claim encompassing the use of these muteins, Biogen improperly extended the monopoly conferred by the '332 patent. And on this issue, again, Biogen's arguments strained credulity to attempt to defend the indefensible. Biogen ignored undisputed expert testimony demonstrating that the use of muteins claimed by the '332 patent were a species of those claimed by the '755 patent. And it pressed a baseless legal argument that the more favorable "two-way test" applied—despite precedent dictating that it did not and facts that come nowhere near establishing that it does. Both of these unreasonable positions, to defend a plainly invalid claim, further support a finding of exceptionality.

A. It Was Undisputed that the Muteins Claimed in the '755 Patent Include Muteins Claimed in the Earlier-Issued '332 Patent.

Biogen argued that Bayer was incorrect to claim that the '332 and '755 patents have a "species-genus relationship" that would render claim 1 of the '755 patent invalid for obviousness-type double patenting. In fact, the evidence on this point was undisputed, and was supported by the testimony of Biogen's own expert.

There was no dispute that the polypeptides of claim 8 of the '332 patent meet the "capable of hybridizing" and "antiviral activity" limitations of claim 1 of the '755 patent, and thus fall within

it. *See* Ravetch Rep. ¶ 123, ECF No. 515-3. Like claim 1 of the '755 patent, claims 5 and 8 of the '332 patent were methods directed to the treatment of specified viral diseases by the administration of a therapeutically effective amount of a polypeptide. Biogen's only expert to address the issue agreed that the genus of claim 1 of the '755 patent includes the polypeptides of the '332 patent: "Q. There's a species/genus relationship between the claims of the '332 patent and the claims of the '755 patent, correct? A. Correct." Green Tr. 634:23-635:4, ECF No. 521-7; *see also* Green Tr. 550:3-25 (hybridization), 559:10-17 (hybridization), 630:2-5 (recombinant polypeptide). Biogen's expert further testified that both the '332 and '755 patents claim methods of using polypeptides, and, with respect to the relationship between those uses, he agreed that "the use of the specific mutein claimed in the '332 patent falls within or is a subset of the use of [IFN-β] and its muteins claimed in the '755 patent."[3] Green Tr. 634:16-21, ECF No. 521-7. It was also undisputed that the muteins claimed by the '332 patent may deviate from the sequence of native IFN-β sequence by only a single amino acid and that they are encoded with DNA capable of hybridizing to at least one of the inserts cited in claim 1 of the '755 patent. Green Tr. 550-62, ECF No. 521-7; Garcia Tr. 53:7-23, ECF No. 521-9 (agreeing that a polypeptide having one or two amino acid changes from native [IFN-β] would

[3] This admission undermines Biogen's assertion to this Court (and unsuccessful argument to the PTO), that someone theoretically could practice the '332 patent by making muteins in a *human* host, or by chemical synthesis, either of which would be outside the "non-human host" limitation of the '755 patent. Particularly given the focus of the '332 patent—and the biotechnology field more broadly—on recombinant expression in non-human host systems, the claims of the '332 patent would be understood to disclose, or alternatively to render obvious, non-human expression. *See* ECF 597 at 10–15; '423 Appl., Non-Final Rejection at 9 (Dec. 10, 2020); *see also Perricone v. Medicis Pharma. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) ("This court rejects the notion that one of these [species] cannot anticipate because it appears without special emphasis in a longer list."). As discussed above, Biogen's expert conceded that the '755 muteins and the '332 muteins have a genus-species relationship. Green Tr. 634:23-635:4, ECF No. 521-7. Biogen's arguments on this point, in fact, were another effort to misdirect the Court. *Compare* ECF No. 559 at 13 (misleading Biogen demonstrative) *with* ECF No. 597 at 13 (Bayer demonstrative).

fall within the scope of the claim). It was thus undisputed that muteins, like those of the '332 patent, that deviated from the native sequence by only one amino acid, were "capable of hybridizing" with a DNA sequence covered by claim 1 of the '755 patent—a proposition to which multiple Biogen experts agreed without suggesting any need for experimental verification.

Yet, at oral argument on Bayer's motions for summary judgment, Biogen suggested that whether the DNA encoding the '332 mutein would hybridize was a factual *dispute*, which *required testing to resolve*, and which precluded summary judgment. Tr. Hr'g Mots. Summ. J. at 162:5-17, ECF No. 750 (" . . . you can't just look at these things, you have to do an experiment, you have to test them."). That assertion was simply not true. There was *never* any dispute that '332 patent covers polypeptides that have anti-viral activity and are encoded by DNA that would hybridize to the inserts in the '755 patent; accordingly, polypeptides within the scope of the '332 DNA are within the scope of claim 1 of the '755 patent. There was no need to "test them" to know this fact—Biogen's own experts admitted it. The examiner in the reexamination has agreed.

B. Biogen's Argument that the Two-Way Test Applied Was Baseless.

Biogen also baselessly argued that the more favorable "two-way test" applied to the double patenting analysis because, that test applies where the PTO and the patentee are both responsible for the delay in causing the later-filed application to issue first, ignoring precedent dictating that the two-way test only applies where the PTO is *solely* responsible for the delay. Biogen then claimed that the PTO *was* solely responsible for the delay, despite conceding that it *chose* not to pursue the method of treatment claims for years. Finally, Biogen argued that the determination of which test applies is a question of fact that precludes summary judgment, again ignoring Federal Circuit precedent that unambiguously states otherwise.

1. There are two theoretically possible tests for a double patenting analysis: (1) the one-way test—applied in every Federal Circuit case since the Berlin Wall fell—which asks whether the

later-expiring claim in the '755 patent is obvious over, or anticipated by, the earlier-expiring claims in the '332 patent, and (2) the two-way test, which also asks whether the claims of the '332 patent are obvious over or anticipated by Claim 1 of the '755 patent. The two-way test is "a narrow exception to the general rule of the one-way test," *In re Hubbell*, 709 F.3d 1140, 1149 (Fed. Cir. 2013), which only applies where the "[PTO] is '*solely* responsible for the delay in causing the second-filed application to issue first,'" *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 n.7 (Fed. Cir. 2001) (quoting *In re Berg*, 140 F.3d 1428, 1437 (Fed. Cir. 1998)) (emphasis in original). The two-way test does not apply where the later expiring "claim could have been presented earlier." *Id.* (quoting plaintiff's intellectual property practice expert).

Biogen's contention that the two-way test should apply because the '332 patent issued first "through no fault of Biogen's" is entirely unsupported by the record and was contradicted by Biogen's own expert, Dr. Doll. *See* Opp. Mot. Summ. J. No. 1 at 4, ECF No. 559; Doll Decl. ¶ 22, ECF No. 567; Doll Tr. 214:23-215:4, ECF No. 504-8. Federal Circuit precedent is unambiguous that the two-way test *only* applies where the PTO is "*solely* responsible for the delay in causing the second-filed application to issue first," without regard for whether the applicant's delay caused or contributed to the first filed patent to issue second. *In re Hubbell*, 709 F.3d at 1149 (quoting *In re Berg*, 140 F.3d at 1437); *Eli Lilly*, 251 F.3d at 968 n.7 (same); *In re Goodman*, 11 F.3d 1046, 1053 (Fed.Cir.1993) (same).

There was no dispute here that Biogen contributed to at least a portion of the delay in issuance of the '755 patent, so that PTO was not solely responsible, and the one-way test must apply—notwithstanding Biogen's attempts to confuse the issue by focusing on what it called the "critical co-pendency period," Opp. Mot. Summ. J. No. 1 at 22, ECF No. 559. Biogen first filed a U.S. application for what would eventually issue as the '755 patent in April 1981. Appl. No.

06/250,609.[4] That application included a number of claims, including a method of treatment claim. In April 1982, the examiner issued a restriction requirement separating the method-of-treatment claim from other categories of claims. '609 Appl, 4/3/81 Restriction Requirement. For seven years Biogen tried and failed to pursue these other claims. It was not until 1989 that Biogen's decided to pursue the method of treatment claim.

As Biogen's patent practice expert (and former Commissioner of Patents) John Doll admitted, "after the [PTO] has issued a restriction requirement, then applicant has the option to file divisional applications to any one or all of the nonelected inventions *at any point in time* after the restriction requirement has been issued." Doll Tr. 214:23-215:4, ECF No. 504-8 (emphasis added); 199:20-22 ("[A]ny time . . . before [the] '609 [application] issued as a patent or went abandoned, you could file a continuing or a divisional application"; the timing was at "Biogen's option."). Biogen could have filed a divisional application claiming the method of treatment *at any time* following the PTO's restriction in 1982. *Nothing* actually *prevented* Biogen from pursuing the claim. *See* Doll Tr. 197:14-19, 199:7-200:3, ECF No. 504-8 ("There was nothing unusual about filing a continuation while the interference was in progress."). Because Biogen's "claim could have been presented earlier," "the PTO was not *solely responsible* for the delay," and so the two-way test does not apply. *Eli Lilly*, 251 F.3d at 968 n.7 (quotation omitted).

Biogen also admitted that it caused at least part of the delay in the issuance of the '755 patent by filing a flawed terminal disclaimer during the so-called "critical co-pendency period," resulting in about a four-month delay completely unattributable to the PTO. Opp. Mot. Summ. J. No. 1 at 22, ECF 559. Even under Biogen's baseless legal theory, its own admissions belie its attempts to blame the PTO for all of the delay. It would be difficult to invent a more paradigmatic example of an

[4] On its face, the '755 patent claims priority to an April 1980 application as well, but Biogen has not contended in this litigation that it is entitled to that earlier date.

exceptional case than a patentee charged with demonstrating that the PTO was solely responsible for the delay attempting to satisfy that test while agreeing that it, not the PTO, was responsible for multiple delays, including waiting seven years to file method claims.

2. Compounding matters, Biogen suggested that this Court must deny Bayer's motion for summary judgment as to obviousness-type double patenting because the dispute about which test for double patenting applied raised a "dispute of fact." Opp. Mot. Summ. J. No. 1 at 14, 23, ECF No. 559. That was yet another misdirection, because "whether the 'one-way' test or the 'two-way' test applies, the dispositive issue here, is one of law." *In re Berg*, 140 F.3d at 1432; *see In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997); *Hubbell*, 709 F.3d at 1149. Nor can Biogen claim ignorance of the controlling authority on this point, as Bayer cited and quoted in its opening brief the Federal Circuit precedent that this determination is a "question of law." Mot. Summ. J. No. 1 at 17, ECF No. 521-22 (quoting *In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009)). Its argument that purportedly disputed facts could avoid summary judgment on obviousness-type double patenting—especially where the parties agreed about the underlying facts—was nothing short of frivolous, and further supports a finding of exceptionality.

IV. Biogen Survived Summary Judgment of Anticipation over the Weissmann Patent by Re-Writing Its Claim, Misleading the Court, and Manipulating Experimental Evidence.

The breadth of claim 1 of the '755 patent also meant that it covered the prior art use of recombinant interferon alpha ("IFN-α"), a polypeptide that was disclosed in U.S. Patent No. 4,530,901 (the "Weissmann Patent"). To avert a summary judgment ruling on this issue, Biogen tried to narrow its claim by (a) baselessly misconstruing the patent's "capable of hybridizing" limitation; (b) redefining what constitutes a positive experimental result for hybridization in a manner inconsistent with the patent's definition of the term and the Court's construction to which it agreed; and (c) burying its own experimental evidence because that evidence might have undermined

its case. Its multiple frivolous and disingenuous arguments, and its attempts to avoid finding out or telling the Court the truth about what testing would show on this issue, are yet further reasons this case is exceptional.

A. Biogen Disavowed the Stipulated Meaning of "Capable of Hybridizing."

To begin with, Biogen advanced an entirely baseless—and belated—claim construction of the "capable of hybridizing" limitation of claim 1 in an effort to avoid anticipation over the Weissmann patent. During claim construction, the parties agreed that "whether a DNA sequence is 'capable of hybridizing'" to the claim 1 DNA inserts depends on whether a Southern blot test "produce[s] a result above background," which indicates that the DNA strand has hybridized. Signals "above background" appear as gray or black bands on a lighter shaded film. (The mechanics of the test are summarized in Bayer's Motion for Summary Judgment No. 6 at 6-11, ECF No. 627-1; Southern blotting is also identified in the '755 patent specification at Col. 48:66-67.) Under the agreed-upon claim construction, if hybridization occurs between a DNA sequence encoding IFN-α and a DNA sequence recited in claim 1, then IFN-α is covered by claim 1, and because Biogen did not dispute that the prior art disclosed recombinant IFN-α to be therapeutically effective in treating viral conditions, claim 1 is anticipated.[5]

The '755 patent and the parties' agreed-upon claim construction also stated that "capable of hybridizing" meant "under hybridizing conditions comprising using, at 68° C, a hybridizing solution that includes 0.75 M NaCl and a washing solution that includes 0.3 M NaCl." *See* Joint Claim Construction Statement at 3, ECF No. 100-1. The parties agreed that the only two experimental

[5] As detailed in Bayer's Motion for Summary Judgment No. 6, if any sequence encoding IFN-α is capable of hybridizing—not just the one disclosed expressly in Weissmann—IFN-α is within the claim. That is because Biogen drafted the claim to include not only DNA sequences that hybridize to the recited DNA inserts, but also DNA sequences that are *degenerate* to those, meaning that they encode the same polypeptides. The issue of degeneracy was undisputed. Bayer Mot. for Summ. J. No. 6 at 12-14, ECF No. 627-1.

conditions that claim 1 limited were temperature and NaCl concentration. *Id.* The claim did not limit other experimental parameters.

Bayer commissioned an expert to test whether DNA encoding IFN-α would hybridize to that encoding IFN-β. ECF No. 627-1 at 14-18. The expert conducted the test according to the enumerated conditions in the '755 patent, as well as the conditions generally used by practitioners in 1980 (the patent's asserted priority date). *Id.* at 14. That experiment revealed that DNA encoding IFN-α did hybridize to two of the DNA inserts listed in claim 1—the "result above background was approximately 63 times more intense" than any other signal for different DNA run in the same test, Moore Decl. at 2-3, ECF No. 626-4—and so was "capable of hybridizing" within the meaning of claim 1 of the '755 patent.

Confronted with this evidence, Biogen proposed a new and nonsensical definition of "result above background" for the Southern blot test that would require a signal as intense as that generated by a positive control.[6] And it argued that the "conditions that Dr. Fiers used, and claimed, [were] designed to capture only DNA sequences that are substantially similar to human interferon-beta and to eliminate non-interferon-beta-like DNA sequences." ECF No. 633 at 27. That argument relied on statements Biogen made in 1983, which Biogen grossly mischaracterized, because the statement was not directed at the hybridization limitation, but to a claim containing the narrower limitation "DNA sequences which hybridize to any of the foregoing DNA inserts and *which code for a polypeptide of the IFN-β type*." *Id.* (citing Ex. 10 at 4, ECF No. 635-10). No such language appears in claim 1 or anywhere else in the '755 patent.

[6] The "positive control" is a DNA sequence identical to the tested sequence—here, IFN-β—which is used to ensure the quality of the experiment. Identical sequences of DNA would be expected to hybridize to each other and so will produce a strong signal above background in a properly conducted experiment.

Biogen's expert re-defined "result above background as" "a signal that approximates the signal that is elicited by a perfectly homologous sequence," *e.g.*, the DNA used as a positive control, Green Rebuttal, ¶ 285, ECF No. 523-6, which is tantamount to requiring that the DNA sequences be identical or nearly identical to be deemed "capable of hybridizing." As Biogen's lawyers and witnesses recognized at every stage in the litigation until they were confronted with experimental evidence of anticipation by Weissman, that is not what "above background" means; this was a radical redefinition of the previously agreed claim construction. Worse, it violated the principle that Rule 30(b)(6) deposition testimony is binding on the party that offers it. *See Sanofi-Aventis v. Sandoz, Inc.*, 272 F.R.D. 391, 393 (D.N.J. 2011) (a party's 30(b)(6) designee's testimony is binding on that party). Biogen's 30(b)(6) designee regarding "[t]he conditions used in hybridization assays by Biogen from 1978 to 1984" testified that "signal above background" means what plain English would suggest: "You can see discrete spots as opposed to sort of general diffuse darkness" and "if it's enough darker that you can see a particular spot that's darker . . . the signal may not be strong" but it's "a signal above background." Meier Tr. 89, ECF No. 627-8. Simply put, there was no basis for this argument, and it is yet another example of Biogen's strained attempts to bend facts and law to preserve its claims.

B. Biogen Misrepresented Its Testing to the Court and Manipulated Its Experimental Evidence

In a final effort to attack Bayer's experimental evidence, Biogen engaged in a pattern of exceptional conduct that included commissioning a competing hybridization experiment, misleading the Court about whether it had done so, cancelling that experiment at the eleventh hour, then misleading the Court *again* that it ran out of time.

After Bayer first served its own testing results during expert discovery, Biogen moved to strike the expert report disclosing and analyzing that testing. Biogen claimed that it was prejudiced because, *inter alia*, Bayer's "actions have frustrated Biogen from conducting its own testing in

response," and represented that it had found a testing lab that first said testing would "take months and then ultimately stated it could not perform such testing at all." Biogen Mot. Strike at 14, ECF No. 457-1. Remarkably, Biogen *had already begun working with a different lab*. Fletcher Decl. ¶ 7, ECF No. 496. Worse, even when asked directly by the Court if it was "still interested in looking for another lab," it remarkably evaded the question rather than confessing that it had found one. Bayer Letter (Dec. 13, 2016), ECF No. 482. Later, once it became clear Biogen would lose the motion to strike, it served an expert report and experimental results from that other lab, justifying its belated disclosure by repeating the misrepresentation: at the time of the motion to strike, it claimed, "it seemed unlikely that Biogen could cure the prejudice caused by Bayer's untimely disclosure because Biogen could not find a laboratory to conduct the requisite Clone 4 experiments." Biogen Letter (Dec. 13, 2016) at 2, ECF No. 479. This was false. Biogen *had already* found a laboratory.

The testing that laboratory performed, however, did not "replicate Bayer's own testing," as Biogen also represented. Biogen Opp. at 7, ECF No. 489. Instead, Biogen's new lab, apparently erroneously, used 10,000 times less DNA than required. Dathe Tr. 316, ECF No. 627-10. Needless to say, that made a signal harder to detect. As the witness Biogen commissioned to perform the test agreed, given the incorrect amount of DNA used, it was wrong for Biogen to suggest that the test showed the sequence was not capable of hybridizing to the claim's inserts. Dathe Tr. 80, ECF No. 627-10 ("[T]he less target sequence, the weaker the signal," and that "if one loads too little target sequence, the signal will not be observable."); *id.* 351–53 (agreeing that a larger amount of DNA might show that Clone 4 was "capable of hybridizing" to the inserts); *see also* Couceyro Tr. 79-80, ECF No. 627-24 ("[A]t some lower levels of DNA, that signal may not be observable either for a perfectly identical positive control or for a nonidentical test sample."). The parties' experts agreed that those experiments cannot be used to assess whether a hybridization signal would be observed using more DNA, such as the one microgram used in Bayer's experiment. Dathe Tr. 305-07, ECF

No. 627-10 ("Q: You can't tell from your experiments one way or the other whether there would be a hybridization signal if you used, for example, a hundred nanograms of HFIF3 and HFIF6? . . . [A]: Correct."); Couceyro Tr. 91-93, ECF No. 627-24. In other words, Biogen *knew* that its experimental testing evidence was flawed—its own attorney hoped (in vain) that the testing lab was mistaken when it conveyed how little DNA it used, *see* Email P. Sandel to J. Dathe (Dec. 19, 2016), ECF 643-3 at 2 ("I'm hoping that ng number [stated in Dathe's email] is the correct one")—and yet, it *still* presented the results to this Court as if it were persuasive evidence that DNA encoding prior-art IFN-α fell outside claim 1. Opp. Mot. Summ. J. No. 6 at 37-39, ECF No. 633.

When Biogen's attorneys discovered that the test had used too little DNA—and thus would be irrelevant—they commissioned another test, using more DNA. Yet at the last-minute Biogen panicked and tried to cover up what was about to be a fatal result. When the follow-up experiment was a mere three days from completion, and all but $400 had been paid to Biogen's expert, Biogen terminated the experiment without explanation. Dathe Tr. 370, 377, ECF No. 627-10 ("Q: Do you have any explanation of why Biogen would want to stop the test three days or a week before you were going to get hybridization results with higher amounts of DNA? [A]: I -- I don't know. Q: Isn't the most logical inference that they were scared about what your results were going to show so they didn't want you to complete it? [A]: That's a possibility.").

Worse yet, Biogen represented to this Court that the experimenter had run out of time. ECF No. 633 at 39. This was yet another misrepresentation. Biogen's counsel had asserted that before the test even began, but that did not deter Biogen, its counsel, or its expert from *starting* the test. *See* Email P. Sandel to J. Dathe (Dec. 22, 2016) ("Unfortunately, we are basically out of time"); Email P Sandel to J. Dathe (Dec. 27, 2016) (directing Dathe to start the experiment), ECF 643-3 at 1-2. It just unilaterally decided not to *finish*. As of December 27, 2016, Biogen's expert was "three days" away from obtaining results when he was "told to terminate the project." Dathe Tr. 367-369,

ECF No. 627-10. There was no deadline, and there was no reason the experiment could not have been allowed to proceed to completion—other than Biogen did not want to see what it would reveal. *See* Dathe Tr. 339-42, 352-78, ECF No. 627-10. Biogen's own expert testified that he ""c[ould]n't think of another explanation" for why Biogen terminated the test other than that it did "not want[] to know the results." Couceyro Tr. 296, ECF No. 627-24.

In multiple ways, therefore, Biogen's handling of the arguments regarding interferon-alpha were exceptional. It willfully distorted the construction of two different claim terms, jettisoned an experimental test at the eleventh-hour to avoid confirming Bayer's evidence that DNA encoding interferon-alpha hybridizes to the claim inserts recited in the '755 patent, and repeatedly misled the Court, about whether it would or could do testing, about what that testing showed, and about why its experiments were never finished. This egregious trifecta supports an exceptional case finding—particularly when combined with Biogen's entire pattern of conduct. *See MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 915-21 (Fed. Cir. 2012).

V. Biogen's Request that the Court Delay Entry of Final Judgment Because the PTO *Might* Issue New Claims Was Frivolous.

Finally, Biogen's meritless efforts to hold onto its patent did not even end when the Federal Circuit ultimately invalidated it. After the Federal Circuit mandate issued, Biogen asked this Court to delay entry of final judgment for at least six months because Biogen had "proposed new claims" in a reexamination of the '755 patent and argued that, if the new claims issued, it would render the invalidity determination "irrelevant." Biogen Letter (Jan. 11, 2021) at 1-2, ECF No. 1115. Biogen's representation that speculative new claims could somehow "render irrelevant" the invalidity determination was preposterous. The Federal Circuit has affirmed the jury's verdict that every *existing* claim of the "'755 patent at issue *in this litigation* is invalid. New claims cannot change that. Moreover, aside from its bizarre argument that this Court should stay a litigation that rightfully had ended, Biogen made no effort to ask the Federal Circuit or Supreme Court to stay the mandate that

it asked this Court to delay—presumably because it knew there was no meritorious argument in favor of such a stay.

Biogen's efforts to the bitter end to forestall final judgment against it, on a patent claim that is invalid for myriad reasons and has been found to be so by a jury, the Federal Circuit, and the Patent and Trademark Office, are truly exceptional.

VI. Bayer's Fee Request is Reasonable.

As a result of Biogen's multiple baseless positions and improper litigation conduct, Bayer seeks $25,261,412.64 in fees to compensate it for the cost of litigating this matter. This fee request is reasonable given the breadth and duration of the case. Section 285 specifies that a court "in exceptional cases" may award "reasonable attorney fees." Courts assess the reasonableness of fee claims with reference to a list of twelve non-exclusive factors, including the "time and labor required," including hourly rates; the "novelty and difficulty" of the case; the "experience, reputation, and ability of the attorneys"; the amount at issue, and the "results obtained." *Hensley v. Eckerhart*, 461 U.S. 424, 430 n.3 (1983) (citations omitted).[7]

As further detailed in the attached Declaration of David M. Krinsky ("Krinsky Decl.") and Exhibits A-G attached, Bayer's fees in this matter are reasonable. First, the number of hours expended on this litigation was reasonable given the scope, duration, and number of issues involved in the case. Among other labor-intensive tasks, over the course of eleven years of litigation, Bayer's counsel: briefed and argued six motions for summary judgment, *see In re Biogen Litig.*, 2:10-cv-2734, ECF Nos. 503, 506, 509, 513, 517, 624; briefed and argued numerous discovery disputes and arguments related to claim construction; took, defended, or attended 35 expert depositions; took or defended dozens of fact witness depositions; and generally researched, synthesized, and presented arguments addressing

[7] The Federal Circuit has recognized that all federal fee-shifting statutes "should be construed uniformly." *Bywaters v. United States*, 670 F.3d 1221, 1228 (Fed. Cir. 2012).

no less than ten separate invalidity defenses—as well as multiple non-infringement ones implicating many of the same frivolous and meritless arguments discussed above—spanning a host of different issues in the patent law. The opening expert report of Bayer's lead expert alone ran to 545 pages. *See* Ravetch Rep., Table of Contents, ECF 515-3. In light of the volume of work required in mounting a complete and successful defense against Biogen's patent infringement claim, the 72,299 hours billed by Williams & Connolly LLP timekeepers was reasonable.

Second, Bayer's counsel charged reasonable hourly rates for each of its timekeepers. For comparison, the American Intellectual Property Law Association releases an economic survey ("AIPLA Report") detailing attorney's fee rates for intellectual property litigators, stratifying the data by a number of factors including geography. The AIPLA Report is frequently relied upon by courts in this District for purposes of assessing the reasonableness of attorney's rates under § 285. *See, e.g.*, *Sundesa, LLC v. Tejarah Int'l Inc.*, 2020 WL 6781579, at *2 (D.N.J. Nov. 17, 2020). According to the 2017 AIPLA Report, which reflects 2016 data, partner billing rates for intellectual property work by law firms nationwide with 101 or more attorneys range from a minimum rate of $233 per hour at the 25th percentile to maximum rate of $965 per hour at the 75th percentile. Ex. D. For the New York-area, including Newark, New Jersey, the average billing rates for partners ranged from $386 per hour (10th percentile) to $930 per hour (90th percentile). Ex. D.

Excluding the average billing rate for one senior partner, the average rates charged by Williams & Connolly LLP partners for this matter all fall on this AIPLA Report billing spectrum. *See* Krinsky Decl., ¶¶ 8, 10; Exs. A, B. The highest rate charged on any billing entry was $1,100 per hour for a senior partner in 2021, five years after the AIPLA reported rates cited above. *See* Ex A. Similarly, the highest average rate (from 2010 to 2021) for a Williams & Connolly timekeeper was $971 per hour. *See* Ex. B. The firm information contained in the Krinsky Declaration and in Exhibits C, D, E, and F thereto reflect that Williams & Connolly LLP's attorneys' responsibilities, professional qualifications,

and accolades justify rates at the upper end of the spectrum.

Third, this case involved a high degree of difficulty because of the breadth and complexity of the issues involved. For example, each of Bayer's six motions for summary judgment addressed different reasons why the '755 patent was invalid, and each involved multiple disputed legal issues.

Finally, Bayer's fee request is reasonable because it was proportionate to the enormous damages claims that Biogen advanced. Biogen's damages expert calculated three different scenarios for the damages that Bayer allegedly owed to Biogen in the event of an infringement verdict in its favor, and the *lowest* of these was $1.4 billion; the highest was $2.3 billion. *See* Murphy Decl. at 7, ECF No. 565 (citing expert report of Kevin Murphy). These damage calculations were only for the period between September 15, 2009, and December 31, 2015, with potential damages continuing to accrue for an additional five years. *Id.* ¶ 14. This was an unambiguously high-stakes litigation, and Williams & Connolly LLP delivered an unambiguous victory for Bayer. Finally, if any discovery is conducted, Williams & Connolly LLP's rates and total amount billed would prove comparable to those of Biogen's attorneys. As a result, this factor also weighs in favor of the reasonableness of Bayer's fee claim. For all of these reasons, Bayer's request for attorney's fees is reasonable.

CONCLUSION

Bayer has endured the burden of this litigation for more than a decade. In more than ten years of litigation, Bayer has spent millions of dollars litigating a case that never should have been brought in the first place and could not have been maintained without baseless argument after baseless argument on Biogen's part.

For all of these reasons, Bayer requests that the Court deem this case "exceptional" under 35 U.S.C. § 285 and award Bayer attorney's fees in the amount of $25,261,412.64.

Dated: April 21, 2021

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